



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0876]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pretesting of Tobacco Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0674. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Pretesting of Tobacco Communications--(OMB Control Number 0910-0674)--Extension

In order to conduct educational and public information programs relating to tobacco use, as authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(D)), and to develop stronger health warnings on tobacco packaging as authorized by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), it is beneficial for FDA to conduct research and studies relating to the control and prevention of disease as authorized by section 301 of the Public Health Service Act (42 U.S.C 241(a)). In conducting such research, FDA will employ formative pretests to assess the likely effectiveness of tobacco communications with specific target audiences.

The information collected will serve two major purposes. First, as formative research it will provide the critical knowledge needed about target audiences. FDA must first understand critical influences on people's decisionmaking process when choosing to use, not use, or quit using tobacco products. In addition to understanding the decisionmaking processes of adults, it is also critical to understand the decisionmaking processes among adolescents (ages 13 to 17), where communications will aim to discourage tobacco use before it starts. Knowledge of these decisionmaking processes will be applied by FDA to help design effective communication

strategies, messages, and warning labels. Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Pretesting messages with a sample of the target audience will allow FDA to refine messages while they are still in the developmental stage. By utilizing appropriate qualitative and quantitative methodologies, FDA will be able to: (1) Better understand characteristics of the target audience--its attitudes, beliefs, and behaviors--and use risk communications; (2) more efficiently and effectively design messages and select formats that have the greatest potential to influence the target audience's attitudes and behavior in a favorable way; (3) determine the best promotion and distribution channels to reach the target audience with appropriate messages; and (4) expend limited program resource dollars wisely and effectively.

In the Federal Register of August 17, 2012 (77 FR 49819), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received, which included one comment that was not PRA-related and beyond the scope of this document, and one comment that was in full support of pretesting tobacco communications. The third commenter indicated that the authorizing statute was incorrectly identified. The correct authorizing statute is section 1003(d)(2)(D) of the FD&C Act. The commenter also indicated that there was not enough information provided about the design and methodology of the pretests and the studies to effectively comment on the collection of information. In response, the information collection is for a broad spectrum of pretests and studies using a variety of methodologies and is dependent on the material being tested and the target audience. Each separate collection and pretest will be submitted for OMB review and approval prior to the collection or pretest being released to the public.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Individual In-Depth Interviews	360	1	360	0.75 (45 minutes)	270
General Public Focus Group Interviews	144	1	144	1.5 hours	216
Intercept Interviews: Central Location	600	1	600	0.25 (15 minutes)	150
Intercept Interviews: Telephone ²	10,000	1	10,000	0.08 (5 minutes)	800
Self-Administered Surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper Reviews	400	1	400	0.50 (30 minutes)	200
Omnibus Surveys	2,400	1	2,400	0.17 (10 minutes)	408
Total (General Public)	16,304				2,644
Physician Focus Group Interviews	144	1	144	1.5 hours	216
Total (Physician)	144				216
Total (Overall)	16,448				2,860

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Brief interviews with callers to test message concepts and strategies following their call-in request to the FDA Center for Tobacco Products 1-800 number.

The number of respondents to be included in each new pretest will vary, depending on the nature of the material or message being tested and the target audience. However, for illustrative purposes, table 1 provides examples of the types of studies that may be administered and estimated burden levels that may be incurred during each year of the 3-year period. Time to read, view, or listen to the message being tested is built into the “Hours per Response” figures.

Dated: January 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-01445 Filed 01/24/2013 at 8:45 am; Publication Date: 01/25/2013]